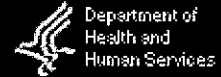


Exhibit D

<http://www.cfsan.fda.gov/~dms/pbguid3.html>



U.S. Food and Drug Administration



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November 2006

Guidance for Industry

Lead in Candy Likely To Be Consumed Frequently by Small Children: Recommended Maximum Level and Enforcement Policy

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**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition (CFSAN)
November 2006**

Guidance for Industry ^[1]

Lead in Candy Likely To Be Consumed Frequently by Small Children: Recommended Maximum Level and Enforcement Policy

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person and does not operate to bind FDA or the public. You may use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate telephone number listed on the title page of this guidance.

I. Introduction

This guidance provides a recommended maximum lead level of 0.1 ppm in candy^[2] likely to be consumed frequently by small children. FDA considers the recommended maximum lead level to be achievable with the use of good manufacturing practices in the production of candy and candy ingredients and to be protective of human health. For additional discussion of the background and rationale underlying this recommended level, see "Supporting Document for Recommended Maximum Level for Lead in Candy Likely To Be Consumed Frequently by Small Children."

In addition to announcing the recommended maximum lead level, FDA as explained below, is rescinding the previous 0.5 ppm guideline for considering enforcement action against candy products likely to be consumed frequently by small children. FDA is prepared to take enforcement action against any candy product containing lead at levels that may pose a health risk. Further, FDA is reiterating its enforcement policy toward the use of lead-based ink on candy wrappers as originally stated in its 1995 letter to the industry on this subject.

FDA considers the issuance of this guidance to be a prudent public health measure consistent with the Agency's policy of reducing lead levels in the food supply to reduce consumers' lead exposure to the lowest level that can be practicably obtained.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. Discussion

A. Recommended Maximum Level for Lead in Candy Likely To Be Consumed Frequently by Small Children

FDA is recommending that lead levels in candy products likely to be consumed frequently by small children not exceed 0.1 ppm because such levels are achievable under good manufacturing practices and would not pose a significant risk to small children for adverse effects. This recommended maximum level of 0.1 ppm for lead in candy likely to be consumed frequently by small children is consistent with the FDA's longstanding goal of reducing lead levels in the food supply to reduce consumers' lead exposure to the lowest level that can be practicably obtained. This recommendation is further discussed in the supporting document for this guidance noted above.

B. Enforcement Policy for Lead in Candy Likely To Be Consumed Frequently by Small Children

Because it is no longer regarded as consistent with the agency's policy of reducing lead levels in the food supply to reduce consumers' lead exposure to the lowest level that can practically be obtained FDA is rescinding the guidance it provided in the 1995 letter that stated that, where frequent consumption of candy products by small children could be anticipated, FDA would consider taking regulatory action against candy with lead levels that exceed 0.5 ppm.

FDA is now prepared to take enforcement action against any candy product containing lead at levels that may pose a health risk. FDA intends to consider several factors in bringing enforcement actions regarding lead in candy, including the level of lead present, the best available consumption data, and the lead exposure that would result from consumption of the product.

C. Enforcement Policy for Use of Lead-Based Inks on Candy Wrappers

FDA is reiterating in this guidance that FDA's policy toward the use of lead-based ink on candy wrappers remains as stated in its 1995 letter to the industry on this subject:

Generally speaking, if lead derived from a lead-based printing ink is found on the portion of the package that directly contacts food or, if such lead could be expected to migrate into the packaged food, the product would likely be regarded as being in violation of the Federal Food, Drug, and Cosmetic Act. Use of the printing ink only on the outer (non-food contact) surface of the package does not ensure that it will not contaminate the food.

Suitable non-lead-based printing inks^[1] are widely available for use in food packaging, and we continue to strongly urge all candy manufacturers, including those whose products are offered for import into this country, to refrain from the use of lead-based printing inks on their packaging materials.

In addition, the use of lead-based printing inks on candy wrappers may subject a firm to regulatory action by the U.S. Consumer Product Safety Commission under the Federal Hazardous Substances Act (see Letter to US candy importers - July 9, 2004 ([PDF](#)) and Letter to candy producers in Mexico (English version) - July 12, 2004 ([PDF](#)) for additional information). Furthermore, the use of lead or lead-based inks in or on packaging, including candy wrappers, is subject to state Toxics in Packaging legislation which has been enacted in nineteen U.S. states, (see Toxics in Packaging Clearinghouse Fact Sheet ([PDF](#)) for additional information).

^[1] This guidance has been prepared by the Office of Plant and Dairy Foods in the Center for Food Safety and Applied Nutrition (CFSAN) at the U.S. Food and Drug Administration.

^[2] We have included within the broad category of candy, "Mexican-style" candy. "Mexican style" refers to candy which contains ingredients popular in Mexico, such as chili and tamarind,

which are not typically found in domestic candy in the U.S. Within the category of "Mexican-style" candy, we have included powdered snack mix products, which are generally made in Mexico and typically contain combinations of salt, chili powder, sugar and flavoring. These products, popular with children and adults, may be sold alongside of candy in retail outlets, and can be consumed directly from the container like candy, as well as being sprinkled onto fruits and vegetables or in beverages.

[3] Non-lead based printing inks may contain incidental lead at trace levels, e.g., < 0.001%, but, do not contain intentionally added lead as would for example lead chromate inks, which can contain > 2% lead.

Supporting Document for Recommended Maximum Level for Lead in Candy Likely To Be Consumed Frequently by Small Children October 2006

Guidance for Industry: Letter to Manufacturers, Importers, and Distributors of Imported Candy and Candy Wrappers June 13, 1995

Consumer Product Safety Commission: Letter to U.S. Candy Importers (available in [PDF](#)) July 9, 2004

Consumer Product Safety Commission: Letter to Candy Producers in Mexico (available in [PDF](#)) July 12, 2004

Toxics in Packaging Clearinghouse Fact Sheet (available in [PDF](#)) January 2005

This document supercedes "Lead in Candy Likely To Be Consumed Frequently by Small Children: Recommended Maximum Level and Enforcement Policy," December 2005

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Hypertext updated by [dav](#) November 24, 2006